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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/783,522	02/20/2004	Roy Lurie	MWS-109RCE	7481
74321	7590	10/27/2008	EXAMINER	
LAHIVE & COCKFIELD, LLP/THE MATHWORKS FLOOR 30, SUITE 3000 One Post Office Square Boston, MA 02109-2127			WHALEY, PABLO S	
			ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/783,522	LURIE ET AL.	
	Examiner	Art Unit	
	PABLO WHALEY	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 09 June 2008.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-51 is/are pending in the application.
 4a) Of the above claim(s) 37-50 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-36 and 51 is/are rejected.
 7) Claim(s) 12 is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Status of Claims

Claims 1-51 are pending. Claims 1-36 and 51 are rejected. Claim 12 is objected to. Claims 37-50 are again withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Objections

Claim 12 is objected to because of the following informalities: Claim 12 (lines 6) is grammatically incorrect, and should recite “gathering data directly from an in situ experimental device...”. Appropriate correction is required.

Withdrawn Rejections

The rejection of claims 1-9, 22, 23, 25-27, 28-30, and 32-36 under 35 U.S.C. 102 (b) as being anticipated by Goryanin et al. is withdrawn in view of applicant’s arguments, filed 06/09/2008.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-36 are directed to a method and a computer-readable medium comprising executable instructions for carrying out a process. For a process to be statutory, it must provide: (1) a practical application by physical transformation (i.e. reduction of an article to a different state or thing), or (2) a practical application that produces a concrete, tangible, and useful result [State Street Bank & Trust Co. v. Signature Financial Group Inc. CAFC 47 USPQ2d 1596 (1998)], [AT&T Corp. v. Excel Communications Inc. (CAFC 50 USPQ2d 1447 (1999))]. As noted in State Street Bank & Trust Co. v. Signature Financial Group Inc. CAFC 47 USPQ2d 1596 (1998), the statutory category of the claimed subject matter is not relevant to a determination of whether the claimed subject matter produces a useful, concrete, and tangible result. The question of whether a claim encompasses statutory subject matter should not focus on which of the four categories of subject matter a claim is directed to a process, machine, manufacture, or composition of matter--but rather on the essential characteristics of the subject matter, in particular, its practical utility. Therefore, for a system and program that carry out a process to be statutory they must also provide a concrete, tangible, and useful result.

In the instant case, the claimed invention as a whole does not recite a physical transformation of matter. Regarding claims 1-11 and 28-36, the instant claims comprise steps that do not result in a physical transformation of matter, as the claimed method steps are not limited to physical steps (i.e. steps done by a user), and therefore encompass non-physical method steps that may be practiced inside of a computer (i.e. *in-silico*). Where a claimed method does not result in a physical transformation of matter, it may be statutory where it recites a result that is concrete (i.e. reproducible), tangible (i.e. communicated to a user), and useful result (i.e. a specific and substantial). In the instant case, the claims ultimately result in

“instructions for saving the modified model in a storage or displaying the modified model on a display device.” The limitation of saving the model in a storage is not a tangible result as nothing is communicated in a user readable format such that it is useful to one skilled in the art. Additionally, instant claims 12-27, also result in “saving the modified model in a storage or displaying the modified model on a display device.” By similar reasoning, the limitation of saving the model in a storage is not a tangible result as nothing is communicated in a user readable format such that it is useful to one skilled in the art. For these reasons, the instant claims are not statutory.

This rejection could be overcome by amendment of the claims to recite that a result of the process is outputted to a display, or to a user, or in a graphical format, or in a user readable format, or by including a result that is a physical transformation. The applicants are cautioned against introduction of new matter in an amendment.

Claims 12-27 are rejected under 35 U.S.C. 101 because these claims are drawn to non-statutory subject matter. These claims are rejected for the following reasons.

Claims 12-21 are non-statutory because they read on abstract ideas. The prohibition on patenting abstract ideas has two distinct aspects: (1) when an abstract concept has no claimed practical application, it is not patentable; (2) while an abstract concept may have a practical application, a claim reciting an algorithm or abstract idea can state statutory subject matter only if it is embodied in, operates on, transforms, or otherwise is tied to another class of statutory subject matter under 35 U.S.C. §101 (i.e. a machine, manufacture, or composition of matter). (See *In re Comiskey*, Fed. Cir., No. 2006-1286, 9/20/07; *Gottschalk v. Benson*, 409 U.S. 63, 175 USPQ 673, 1972).

In the instant case, claims 12-21 do not qualify as a statutory process because the method steps that are critical to the invention are "not limited to a particular apparatus or machine." To qualify as a statutory process, the critical method steps recited in claims 12-21 should positively recite the other

statutory class (the thing or product) to which it is tied, for example by identifying the apparatus that accomplishes the method steps, or positively recite the subject matter that is being transformed, for example by identifying the material that is being changed to a different state or thing. Nominal data gathering or post solution activity steps in the claimed subject matter will not be considered sufficient to convert a process that otherwise recites only mental steps into statutory subject matter. Preamble limitations that require the claimed process to comprise machine implemented steps will not be considered sufficient to convert a process that otherwise recites only mental steps into statutory subject matter. The applicants are cautioned against introduction of new matter in an amendment.

In addition, claims 22-27 are drawn to an apparatus comprising means for carrying out a process. As the claimed apparatus does not comprise any physical components, and as the claimed processes are not functionally related to any hardware or software components, the claimed apparatus broadly reads on a software program, *per se*, which by itself is non-statutory subject matter.

Response to Arguments

Applicant's arguments, filed 06/09/2008, that the claims are now statutory in view applicants amendments filed 06/09/2008 have been fully considered. In response, claims 1-36 ultimately result in "saving the modified model in a storage or displaying the modified model on a display device." The limitation of "saving the model in a storage" is not a tangible result as nothing is communicated in a user readable format such that it is useful to one skilled in the art. For these reasons, the instant claims are not statutory. Therefore this rejection is maintained. In addition, a new ground of rejection has been applied.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C.102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 12-19, 21, 24, 28, and 31 rejected under 35 U.S.C. 102 (e) as being anticipated by Potts et al. (US Pat. No. 6,882,940; Filed Aug. 10, 2001).

Potts teaches a computer programs for predicting a hypoglycemic event in a subject [Abstract]. The system comprises a device, microprocessors, and software (i.e. instructions) for gathered directly from a transdermal sampling system at set time intervals [Col. 2], which shows gathering data directly from an in situ device on which an ongoing experiment is being conducted, as in claims 1, 12, 22, and 28. Potts teaches generating predicted glucose measurement values (i.e. expected results) [Col. 3, lines 40-60], as in claims 1, 12, 22, and 28. Potts teaches comparing skin conductance readings (i.e. in situ experimental data) with threshold values to determine hypoglycemic events (i.e. expected results) [Reference claims 1 and 25], and teaches correlating (i.e. comparing) blood glucose measurements with “out of sample” predictions made the model [Col. 18, lines 45-67], as in claims 1, 12, 22, and 28. Potts teaches steps for modifying the predictive model based on comparisons to gathered blood glucose values and parameters

need to minimize model error [Col. 18, lines 45-60], which shows modifying a model based on comparison to correct the model, as in claims 1, 12, 22, and 28. The system allows for the storage of data to memory [Col. 16, lines 55-65]. Potts teaches an alert signal (i.e. event signal) generated when glucose amount is outside of the predetermined range of values [Col. 7, lines 20-23], as in instant claims 15, 24, and 31. Potts teaches a prediction system (i.e. modeling environment) allowing for user-settable threshold levels [Col. 13, lines 20-25], which is a teaching for modifying the model based on optimization means (i.e. thresholding), as in claim 12. Potts teaches methods for extracting glucose from a subject glucose into reservoirs and techniques and/or devices for generating glucose data [Col. 3, lines 25-35], which shows gathering and analyzing in situ data, as in claims 12 and 22. Potts teaches the display, operative connection, and wireless transmission of data [Col. 18, lines 5-25], as in instant claims 13, 14, and 18. The Glucowatch prediction system (i.e. modeling environment) allows for user-settable threshold levels [Col. 13, lines 20-25] and comprising an LCD screen and user interface [Col. 16, lines 60-65], as in instant claims 16-17. A predictive Taylor-Series expansion model for adjusting glucose values to predict future values [Equation (7), Reference claim 7], which is a teaching for generating a refined model as in instant claim 19. The GlucoWatch biographer comprises a microprocessor (i.e. analyte monitoring device and display unit) for measuring and analyzing glucose levels from a subject via ionophoresis [Col. 7, lines 15-23], which is a teaching for in situ experimentation and a device as in instant claim 21.

Response to Rejections

Applicant's arguments, filed 06/09/2008, that Potts does not disclose modifying the model of the biological process based on the comparison to correct the model of the biological process have been fully considered. In response, Potts teaches steps for modifying the predictive model based on comparisons to

gathered blood glucose values and parameters need to minimize model error [Col. 18, lines 45-60], which shows modifying a model based on comparison to correct the model, as in claims 1, 12, 22, and 28.

Applicant's arguments, filed 06/09/2008, that Potts does not disclose comparing the generated result to the data gathered from the experimental device have been fully considered. In response, Potts teaches comparing skin conductance readings (i.e. in situ experimental data) with threshold values to determine hypoglycemic events (i.e. expected results) [Reference claims 1 and 25], and teaches correlating (i.e. comparing) blood glucose measurements with "out of sample" predictions made by the model [Col. 18, lines 45-67]. Therefore, this rejection is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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Claims 1-30, 32-36, and 51 are rejected under 35 U.S.C. 103(a) as being made obvious by Goryanin et al. (Bioinformatics, 1999, Vol. 15, No. 9, p.749-758), in view of Bubendorf et al. (Journal of Pathology, 2001, Vol. 195, p.72-79).

The instantly rejected claims are drawn to a computer-readable medium, method, and apparatus for generating results by executing a model, gathering data from an in situ device, comparing generated results to data gathered from the experimental device, modifying the model based on comparison data, and saving the model in storage or displaying the modified model on a display device.

Goryanin teaches a method, system, and program (*DBsolve*) comprising models for the mathematical simulation and analysis of cellular metabolism and regulation. In particular, Goryanin teaches analysis models (i.e. simulation engines) model metabolic pathways, receive input, generate output, and display results via the operably connected model designer [Fig. 1 and Fig. 3]. The model is presented using a block diagram [Fig. 1]. Goryanin teaches an analysis environment in communication with said simulation engine and comparing model data to experimental data for optimization [Fig. 1] and [p.753, Col. 2, ¶ 2]. Goryanin teaches instructions for model refinement based on a comparison of the applied model parameters (i.e. expected results) with observed experimental data [See p.753, Col. 1, ¶2 and Fig. 1]. Goryanin teaches functions for saving or transferring models or data files [See p.750, Col. 1, ¶2 and Fig. 4A]. Goryanin teaches an optimized curve (i.e. event) when the difference between experimental and theoretical data points is calculated according to an absolute value [p.755, Col. 1, ¶ 1]. Goryanin teaches a modeling environment in communication with said analysis models and Fitter/Optimizer [Fig. 1] comprising constructing a model and a GUI for accessing the model and accepting user commands [Fig. 2]. Goryanin teaches inputting experimental data for refining the biological model [p.753, Col. 2, ¶ 2], wherein data is gathered from an “experimental platform” and/or

“experimental device”. *DBsolve* is computer-readable program (i.e. article of manufacture) functionally operating on a computer system to carry out the above method steps.

Goryanin does not specifically teach gathering data from an *in situ* device on which an ongoing *in situ* experiment is conducted, as recited in claims 1, 12, 22, 28.

Goryanin does not specifically teach gathering microarray data or gathering data from a gene chip, as in claims 10, 11, and 20.

Bubendorf teaches a method of high-throughput *in situ* experimentation using tissue microarray (TMA) technology [Abstract]. Bubendorf also teaches displaying *in situ* TMA experiments [Fig. 5] and related data sets [Table 1], as in instant claims 12 and 20. Bubendorf does not specifically teach “ongoing” *in situ* experiments. However, this limitation would have been obvious to one of ordinary skill in the art since they employ a computer-assisted method. The rationale would have been to increase the number of data analyzed to improve statistical results in a clinical setting [Introduction].

It would have been obvious to someone of ordinary skill in the art at the time of the instant invention to use the computer analysis program of Goryanin et al. in combination with the microarray data sets taught by Bubendorf et al., since Goryanin et al. suggest their model can analyze data from various experimental sources [Fig. 1]. One of ordinary skill in the art would have been motivated to combine the above teachings in order to accelerate tumor research using high-throughput *in situ* technologies [Bubendorf et al., Abstract], resulting in the practice of the instant claimed invention with predictable results.

Response to Arguments

Applicant's arguments, filed 06/09/2008, that Goryanin does not teach gathering data directly from an in situ experimental device on which ongoing experiments are being conducted has been fully considered but is moot in view of the new ground of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pablo Whaley whose telephone number is (571)272-4425. The examiner can normally be reached on 9:30am - 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached at 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Pablo S. Whaley/

Patent Examiner

Art Unit 1631

/John S. Brusca/

Primary Examiner, Art Unit 1631